June 2015

ADDITIONAL COMPETENCES TO THE BULGARIAN DRUG AGENCY PROVIDED BY THE AMENDMENTS OF THE MEDICAL DEVICES ACT

Background

On 26th May 2015, the Amendment and Supplement to the Medical Devices Act ("MDA") entered into force, following its publication in the State Gazette.

The amended act ensures compliance with EU Regulation No 920/2013 (the "Regulation"), which aims to achieve better health and safety levels in the use of medical devices throughout the European Union.

The amendments of the MDA grant the Bulgarian Drug Agency ("BDA") additional competences. The authority is expected to assess, designate, notify and monitor the so called "notified bodies", i.e. organisations accredited by a Member State to assess whether medical devices meet certain preordained standards and health and safety regulations. In this manner, apart from supervising the market for the safety of medical devices, the authority shall also designate and monitor the notified bodies. Prior to the current amendments, assessment and control over the notified bodies was conducted by the State Agency for Metrological and Technical Surveillance.

The amended act provides different terms for assessment, depending on the type of medical device. When it comes to in-vitro devices, the assessment period is 4 months. As far as other medical devices go, such as implantable devices, the assessment period is set to a maximum of 6 months. The BDA shall carry out regular inspections of the notified bodies every 12 or 18 months, depending on the number of clients.

As of now, the revenant bodies of the Member States are expected to exchange information about the notified bodies that have successfully passed their assessments, through the EU information system NANDO (New Approach Notified and Designated Organisations). Reports on the eligibility of candidates made by the Members States and the European Commission should also be published in the system. As a result, the designating authorities of other Member States are given the opportunity to access the information published in the report. Information about certificates, which have been denied, temporarily invalidated, or revoked, will also be exchanged through NANDO.

The prospects are that the revised Medical Devices Act amendments would have a positive impact on the market thanks to the increased regulatory efficiency and a more advanced level of safety in the use of medical devices.

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